

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Pau et al.

Serial No.: 09/449,854

Filed: November 26, 1999

For: PRODUCTION OF VACCINES

Examiner: M. Hill

Group Art Unit: 1648

Attorney Docket No.: 2578-4240US

BUDAPEST TREATY DECLARATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Ronald Brus, hereby certify that I am the Chief Executive Officer of Crucell Holland BV ("Crucell") and declare that:

1. I am informed and believe that Crucell is the assignee of U.S. patent application serial no. 09/449,854.

2. I am informed and believe that Crucell made a deposit of the PER.C6 cell line, under ECACC deposit number 96022940 under the provisions of the Budapest Treaty with the Centre for Applied Microbiology and Research Authority (European Collection of Animal Cell Cultures), Porton Down, Salisbury, Wiltshire SP4, QJG, United Kingdom, an International Depository Authority, on February 29, 1996.

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3. On behalf of Crucell, I state that all restrictions upon public access to the deposit (except those permitted by 37 C.F.R. § 1.808(b)) will be irrevocably removed upon the grant of a U.S. patent on this U.S. patent application, and the deposit will be replaced if viable samples cannot be dispensed by the depository.

4. I am informed and believe that the deposit was accepted by the International Depository Authority, effective at least as early as February 29, 1996.

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the U.S. Code and that such willful false statements may jeopardize the validity of the patent.

Date: 24-08-05
Dr. Ronald Brus



Centre for Applied Microbiology and Research & European Collection of Cell Cultures

This document certifies that Cell Culture
(Deposit Ref. 96022940) has been accepted as a patent deposit,
in accordance with
The Budapest Treaty of 1977,
with the European Collection of Cell Cultures on 29TH February 1996

P J Packer

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Dr P J Packer
Quality Manager, ECACC

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BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

TO

INTERNATIONAL FORM

CRUCCELL HOLLAND B.V.
ARCHIMEDESWEIG 4
PO BOX 2048
2301 CA LEIDEN
THE NETHERLANDS

NAME AND ADDRESS
OF DEPOSITOR

I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the
DEPOSITOR:
PER C6

Accession number given by the
INTERNATIONAL DEPOSITARY AUTHORITY:
96022940

II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

☒ A scientific description

☐ A proposed taxonomic designation

(Mark with a cross where applicable)

III. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I above,
which was received by it on 29th February 1996 (date of the original deposit)¹

IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International
Depositary Authority on (date of the original deposit) and
A request to convert the original deposit to a deposit under the Budapest Treaty
was received by it on (date of receipt of request for conversion)

IV. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Dr P J Packer

Signature(s) of person(s) having the power
to represent the International Depositary
Authority or of authorized official(s):

Address: ECACC
CAMR
Porton Down
Salisbury SP4 0JG

Date: 25/2/01 PJPacker

1 Where Rule 6.4(d) applies, such date is the date on which the status of international depositary authority was acquired

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO

CRUCELL HOLLAND B.V.
ARCHIMEDESWEG 4
PO BOX 2048
2301 CA LEIDEN
THE NETHERLANDS

VIABILITY STATEMENT

Issued pursuant to Rule 10.2 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified on the following page

NAME AND ADDRESS OF THE PARTY
TO WHOM THE VIABILITY OF STATEMENT
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
<p>Name: CRUCELL HOLLAND B.V.</p> <p>Address: ARCHIMEDESWEG 4 PO BOX 2048 2301 CA LEIDEN THE NETHERLANDS</p>	<p>Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY: 96022940</p> <p>Date of the deposit or of the transfer: 29th February 1996</p>
II. VIABILITY STATEMENT	
<p>The viability of the microorganism identified under II above was tested on ². On that date, the said microorganism was</p> <p><input checked="checked" type="checkbox"/> ³ viable</p> <p><input type="checkbox"/> ³ no longer viable</p>	

1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).

2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.

3 Mark with a cross the applicable box.

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED ⁴

V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Dr P J Packer
ECACC CAMR
Address: Porton Down
Salisbury
Wiltshire
SP4 0JG

Signature(s) of person(s) having the power
to represent the International Depositary
Authority or of authorized official(s):

Date: 26/2/01 P. Shuck

⁴ Fill in if the information has been requested and if the results of the test were negative.